determination. 22 drugs met NICE's EOL-SPP for the indication for which they were being appraised. Twelve of these drugs had the EOL-SPP criterion applied to the only indication for which they were licensed. The EOL-SPP criterion was applied to the cumulative populations of ten drugs which had marketing authorization for more than one indication. The seven drugs that did not meet the EOL-SPP criterion all had individual indications which were within the number of what is considered acceptable (≤7,000), but had total cumulative populations that were greater. Two STAs in particular stand out. The appraisal committee accepted that panitumumab met the EOL-SPP criterion for its current indication but noted that the EMA recommended a marketing extension which would raise the expected patient population to 10,000. In its final appraisal determination for abiraterone NICE overturned its original decision that the drug did not meet the EOL-SPP criterion, even though it noted that abiraterone may be recommended for a marketing extension for a greater patient population. **CONCLUSIONS:** There is no evidence to suggest NICE applies the EOL-SPP to the cumulative populations of currently licensed indications plus potential future indications.

PCN150

COMPARISONS OF QALYS GAINED, COST PER QALY GAINED AND ASMRS FOR 38 ANTICANCER DRUGS IN FRANCE AND THE UK: VIVE LA DIFFERENCE?

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OBJECTIVES: To compare the contrasting approaches in France and the UK for assessing the value added by new drugs **METHODS:** We reviewed the technology appraisals performed by the National Institute for Health and Clinical Excellence (NICE) on 38 anticancer drugs in the UK from September 2003 to January 2012. Estimates of the quality-adjusted life-years (QALYs) gained and incremental cost per QALY gained were then compared the assessments of the Amélioration du Service Médical Rendu (ASMR) made by the Haute Autorité de Santé (HAS) in France for the same drugs in the same clinical indications. **RESULTS:** In the UK, the estimates of QALYs gained ranged from 0.018 to 1.85 and estimates of incremental cost-per QALY from £1800 to £458,000. The estimate of incremental cost per QALY was a good predictor of the level of restriction imposed on the use of the drug concerned. Patient access schemes, which normally imply price reductions, were proposed in 45% of cases. In France, the distribution of ASMRs was 1, 16%; 2, 8%; 3, 21%; 4, 24%; 5, 24%; and uncategorized/ non-reimbursed, 8%. Since ASMRs of 4 and above signify minor or no improvement over existing therapy, these ratings imply that, in around half the cases, the drugs concerned would face price controls. Overall, the assessments of value added in the two jurisdictions produced very similar results. A superior ASMR rating was a good predictor of both higher QALYs gained and a lower incremental cost per QALY. **CONCLUSIONS:** We conclude that, despite the contrasting approaches employed in France and the UK for assessing the value added by new drugs, the overall assessments of value added produced very similar results. However, the implications of these assessments for patient access to, and prices of, anticancer drugs in the two jurisdictions require further investigation.

PCN151

HTAS FOR THE DEADLIEST DISEASES: WHAT CAN WE LEARN FROM MULTI-NATIONAL COMPARISONS OF ONCOLOGY AND CARDIOLOGY HEALTH TECHNOLOGY ASSESSMENTS?

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OBJECTIVES: To examine the similarities and differences in the HTAs conducted in 6 countries in the last 5.5 years in the areas of cardiology and oncology, the therapeutic areas of greatest mortality. **METHODS:** We reviewed and abstracted information from 768 cardiology and 960 oncology HTAs conducted from January 1, 2007 to June 23, 2012. Our primary focus was those made by the following public organizations: Canadian Agency for Drugs and Technology in Health, Haute Autorite de Sante, Institute for Quality and Efficiency in Health Care, National Institute for Clinical Excellence, Pharmaceutical Benefits Advisory Committee, Medical Services Advisory Committee, and the Agency for Healthcare Research and Quality. For comparative purposes and overall interest, we also studied the HTAs of the following private American organizations: BlueCross BlueShield Technology Evaluation Center, California Technology Assessment Forum, Drug Effectiveness Review Program, Healthcore/Wellpoint, Institute for Clinical and Economic Review, and the MedCo Research Institute, and the multinational Cochrane Collaboration. Finally, we looked at the American Recovery and Reinvestment Act generated CER grants recently made by the federal government to the National Institutes of Health and the Department of Health and Human Services to determine any new directions in the US. Cardiology HTAs were divided into 12 sub-therapeutic categories; oncology 18 for ease of analysis. Variables analyzed included specific subject of HTA and analytic methods, date of release, and results. **RESULTS:** Market entry of drugs and selected devices tended to affect HTA content and timing; country processes for review also affect these variables and results. HTAs of other single interventions and multiple modality comparisons were more variable as to timing, content, and results. **CONCLUSIONS:** Both the commonalities and differences found in the HTAs lend themselves to the examination of potential "economies" of evidence assessment and bases for optimal patient care. The authors provide suggestions for policy makers.

PCN152

PATIENT-RELEVANT ENDPOINTS (PRE) IN ONCOLOGY - CURRENT ISSUES IN THE CONTEXT OF EARLY BENEFIT ASSESSMENT (EBA) IN GERMANY: AN INDUSTRY PERSPECTIVE

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OBJECTIVES: The German AMNOG health care reform includes a mandatory EBA of innovative medicines at launch. As per German social code, EBA is based on registration trials and must include evaluation of the patient-relevant, therapeutic effect of the new medicines compared to an appropriate comparator as defined by the Federal Joint Committee (G-BA). Current EBA decisions released have unveiled issues regarding the acceptance of some PRE as G-BA and IQWiG are grading the endpoints, focusing on overall survival (OS) as the preferred endpoint in oncology. **METHODS:** A task force under the auspices of the German Association of Research-based Pharmaceutical Companies (vfa) was appointed. Members were experienced German outcomes research, medical, HTA and biostatistics researchers in industry. After agreement on core assumptions developed and outlined by the Task Force, a draft position was prepared. Input on iterative versions was solicited from a panel of reviewers from industry and external stakeholders. **RESULTS:** Distinctive features of registration trials in oncology need to be considered when these studies form basis for EBA, especially in cancer indications with long post-progression survival time; and with several consecutive therapeutic options available following progression. Besides, ethical committees, caregivers and patients often demand cross-over-designs diluting over the treatment effect on OS. Also, regulatory authorities require evaluation of morbidity-related study endpoints including survival of patients without their disease getting worse (i.e., progression-free survival). Fear of progression is a key feature in oncological conditions. Furthermore progression usually requires treatment changes, another strong indicator for its relevance to patients. **CONCLUSIONS:** PRE in oncology depend on tumor- and tumor-stage-specific factors. For decades, endpoints have been thoroughly evaluated, resulting in specific guidelines and clinical trial programs that were developed in-line with regulatory guidance. This extensive knowledge and experience should be fully acknowledged during EBA when assessing the patient-relevant benefit of innovative medicines in oncology.

PCN153

APPLICATION OF REAL WORLD DATA TO INFORM A BREAST CANCER DECISION - ANALYTIC MODEL IN AUSTRIA AND THE U.S - PRELIMINARY OUTCOMES OF DATA COLLECTION

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OBJECTIVES: A Breast Cancer Outcomes & Policy (BCOP) microsimulation model is being developed to evaluate the 21-gene recurrence score assay that guides adjuvant chemotherapy in Austria. The goal is to adapt the model to a United States (US) context using real-world data from the Huntsman-Cancer-Institute (HCI) in Utah. We aim to study the impact of real-world data and country-specific settings on cost-effectiveness results. **METHODS:** The BCOP-model simulates a hypothetical cohort of 50year old women over a lifetime time horizon using a discrete-event-simulation. To inform this model, a cohort of early breast cancer patients was identified at the HCI based on ICD-9 codes(174.0-174.9) and inclusion in the HCI registry for invasive breast cancer from 2005-2010. Patients were included with stage I to IIIa disease at diagnosis, documented curative intent surgery, use of endocrine therapy, and lack of HER2 directed therapies. Patients receiving adjuvant chemotherapy were identified. Price for chemotherapy was based on average wholesale price (AWP). **RESULTS:** A total of 367 patients with early stage breast cancer were identified with a mean age of 58.2 years. There were 123 patients (33.5%) treated with adjuvant chemotherapy. Among the 123 patients treated with chemotherapy, 21%, 64.2% and 14.6% were stage I, II and IIIa respectively; which comprised 12.3%, 57.7%, and 64.3% of all stage I, II, and IIIa patients, respectively. The predominate chemotherapy regimen was doxorubicin and cyclophosphamide with or without paclitaxel for 72% of patients. The AWP for this regimen is $4476 with and $1507 without paclitaxel, respectively; the AWP of Oncotype Dx is $4175. One of the challenges faced during model development was that many of the variables needed require chart reviews. **CONCLUSIONS:** Extraction of data from a real-world breast cancer cohort provided reference data on treatments and costs to inform the BCOP- model.

PCN154

ARE POPULATION-BASED REGISTRIES A SUITABLE TOOL FOR OUTCOMES RESEARCH IN CANCER? EXPERIENCES FROM FOUR REGISTRIES

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OBJECTIVES: Population-based registries provide insights into quality of care and inform reimbursement decisions. This study aims to investigate whether registries are a suitable tool for outcomes research in assessing drug use and real-world cost-effectiveness in cancer. **METHODS:** We used four Dutch population-based registries to conduct outcomes research. Patients for the registries were included regardless of prognosis or treatment: 55% and 40% of all Dutch patients in metastatic renal cell cancer (mRCC) and three haematological cancers, respectively.